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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852



MERCK
Research Laboratories

RE: Docket No. 00N-1534
Agency Information Collection Activities; Proposed Collection;
Year 2000 Continuation of National Surveys of Prescription Drug Information
Provided to Patients

Merck & Co., Inc. is a leading worldwide, human health product company. As a leading healthcare company, Merck supports the education of patients about prescription medicines. Over the past years, Merck has developed patient information programs and has worked with the Food and Drug Administration (hereafter referred to as the Agency) to voluntarily develop Patient Package Inserts (PPIs). In addition, Merck participated in the Keystone Steering Committee to develop the *Action Plan for Provision of Useful Prescription Drug Information* for patients (hereafter referred to as The Action Plan). Because of our experience in developing PPIs, Merck is interested in and well-qualified to comment on this FDA proposal regarding continuation of national surveys of prescription drug information provided to patients.

In a letter dated February 9, 1998, Merck commented on this same topic under Docket 97N-0488. Comments offered in the 1998 letter relevant to Docket 00N-1534 are repeated, where applicable, as we comment on the following topics:

Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

It is useful to repeat the survey to establish a trend in receipt of patient information over many years. However, as the survey questions are not provided, it is impossible to determine whether the data generated by the survey will have practical utility.

The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

The estimates of approximately two minutes per screening call and approximately 20 minutes per survey call appear reasonable. Merck agrees that respondents should be asked to complete the survey in minimal time (approximately 20 minutes). However, because the survey questions are not provided, it is impossible to determine whether the Agency's estimates of the burdens of the proposed collection of information and screening are accurate.

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Year 2000 Continuation of Nat. Surveys of Prescription Drug Information Provided to Patients

Ways to enhance the quality, utility, and clarity of the information to be collected, while minimizing the burden of collection on respondents.

Because the survey questions are not provided, it is impossible to comment on this topic. In the future, it would be useful if the Agency could make copies of the survey readily available.

Use of automated collection techniques, and other forms of information technology.

It should be possible to conduct part of the survey via the Internet for patients who order prescription drugs from on-line pharmacies.

Conclusions

It is useful to continue to collect information concerning prescription drug information provided to patients through telephone and electronic methods. However, as stated in this letter, it is difficult to fully assess the utility of such a survey without a clear understanding of the questions to be asked. The underlying assumption that the Agency's collection of information from patients could justify a greater Agency role in developing patient education information would be strengthened through a more public disclosure of survey methods, questions, and validation. Similarly, an analysis of the methodology might also identify gaps in information being collected, which may incorrectly lead the Agency to false assumptions about the need for greater involvement in patient information where no such need exists.

We appreciate the opportunity to comment on this action.

Sincerely,



Bonnie J. Goldmann, M.D.

Vice President

Regulatory Affairs, Domestic

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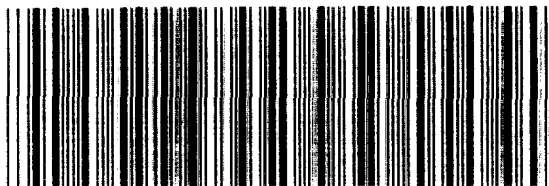
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